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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,327	04/12/2001	Samuel J. Danishefsky	2003080-0081(SK-719-Z)	3477

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EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/833,327

Applicant(s)
Danishefsky et al

Examiner
Karen Canella

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 108-119 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 112 and 113 is/are allowed.
- 6) ☒ Claim(s) 108-111 and 114-119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

1. Acknowledgment is made of applicants election of the required species; however, after review and reconsideration, the species requirement of Paper No. 7 is withdrawn.
2. Claims 108-119 are pending and under consideration.
3. Please note that the preliminary amendment regarding the cross-referencing of related application was entered in the first line of the specification; however, applicant did not direct the deletion the original text, therefore the application contains redundant references to prior applications.

Specification

4. The disclosure is objected to because of the following informalities: the reference on page 12, line 30 to the work of Jefferey et al is incorrect. The correct page number for the publication in Nature Structural biology is page 466..

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 109, 111, 114, 115 and 117-119 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The recitation of "a composition comprising the compound of claim 108" does not impart patentable distinctness to the product of claim 108. Amendment of the claim to remove the word "optionally" is recommended.

Claims 109 and 115 recite "M2 linker" without defining it as such.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

8. Claims 108, 110, 114 and 116 are rejected under 35 U.S.C. 102(b) as being anticipated by any of Windmuller et al (Tetrahedron Letters, 1994, Vol. 35, pp. 7927-7930) or Helland et al (Journal of Carbohydrate Chemistry, 1992, Vol. 11, pp. 77-88). Claim 108 is drawn to a compound which contains the determinant::(Fuc Alpha (1-2)) Gal Beta (1-4) (Fuc Alpha 1-3) GlcNAc Beta (1-3) Gal Beta (1-4) (Fuc Alpha (1-3)) GlcNAc beta (1-3). Claim 110 is drawn in part to the compound of claim 108 which contains the above determinant in addition to an additional Gal Beta (1-4) Gal Beta (1-O) () resulting in the determinant (Fuc Alpha (1-2)) Gal Beta (1-4) (Fuc Alpha 1-3) GlcNAc Beta (1-3) Gal Beta (1-4) (Fuc Alpha (1-3)) GlcNAc beta (1-3) Gal Beta (1-4) Gal Beta (1-O). Claim 114 is included with this group as it is lacking a specific embodiment which would render the composition patentable distinct from the molecule of claim

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108. Claim 116 embodies the composition of claim 114 wherein the molecule is structurally defined as in claim 110.

Windmuller et al disclose the chemical synthesis of the aforesaid determinant of claim 110 (page 7929, structure 2c) , wherein $r = 1$, $m = 0$, and $n = 1$, and wherein R is a substituted alkyl group ($Sp = (CH_2)_8 CO_2Me$ (page 7927)).

Helland et al disclose the chemical synthesis of the aforesaid determinant of claim 110 (page 80, figure 13) wherein $r = 1$, $m = 0$, and $n = 1$, and wherein R is a substituted alkyl group $((CH_2)_2-C_6H_4-(CF_3ONH))$.

9. Claims 108, 110, 114-116 are rejected under 35 U.S.C. 102(b) as being anticipated by Nudelman et al (The Journal of Biological Chemistry, 1986, Vol. 261, pp. 11247-11253)

The embodiments of claims 108, 110, 11 and 116 are recited above. Claim 115 is drawn in part to the composition of claim 114 wherein the compound is bound directly to a lipid.

Nudelman et al disclose the isolation and structural determination of the aforesaid determinant of claim 110 (Structure 2) wherein $r = 1$, $m = 0$, and $n = 1$, wherein the determinant further comprises a linker of $-(CH_2)_s$, wherein $s = 2$, -and wherein $q = 0$ for $(cross\ linker)_q$, and wherein the carrier is a lipid (phosphosphingosines, page 11251, figure 4B), thus fulfilling the specific embodiments of claims 108, 110, 114 and 116, drawn to specific structural determinants and

claim 115 drawn to the compound being bound directly by a lipid.

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10. Claims 108, 110, 114-116, 118 and 119 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaizu et al (The Journal of Biological Chemistry, 1986, Vol. 261, pp. 11254-11258). The embodiments of claims 108, 110, and 114-116 are recited above. Claim 118 specifically embodies the composition of claim 114 wherein the immunological adjuvant is bacteria or liposomes. Claim 119 is drawn in part to said bacteria of *Salmonella minnesota*.

Kaizu et al teach a composition of *Ley trifucosylceramide* and *Salmonella minnesota* cells (Page 11254, second paragraph under the heading "Materials and Methods") which meets the specific structural limitations of the claims as it is the same molecular determinant as that disclosed by Nudelman et al, *supra*.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentable distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. *In re Berg*, 140 F. 3d 1428, 46 USPQ2d 1226 (Fed Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).


13. Claims 108, 110, 114 and 116 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 10 of copending Application No. 09/794,905. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 5 and 10 of the '905 application are drawn in part to an affinity matrix comprising the KH-1 antigen and thus can anticipate the instant claims drawn to a compound which contains the structural determinant of instant claim 108 and the compound of claim 108 wherein $r = 1$, $m = 0$, and $n = 1$, and wherein R is a substituted alkyl group. Claims 114 and 116 are included in this group as the recitation of a "composition" in the preamble does not impart patentable distinctness to the product.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

January 13, 2003
